## REMARKS

Status of the Claims

Claims 1-51 are pending in the present application. Claims 29, 34, 35, and 45 have been amended to more closely correlate the subject matter of the apparatus claims to the process claims. As described in greater detail below, these amendments should enable the process claims to be examined along with the elected claims (i.e., with Claims 1-28) of Group I.

Restriction Requirement

The Examiner indicates that there are three groups of patentably distinct inventions defined by the claims of this application, as follows:

Group I is directed to a medical simulator and includes Claims 1-28.

Group II is directed to a method for making a medical simulator, including Claims 29-44.

Group III is directed to a method of using a medical simulator and includes Claims 45-51.

Status of Claim 28

The Examiner has indicated that Claim 28 is an apparatus claim that should be included in Group I. However, Claim 28 recites a method for making an apparatus. Applicants respectfully request clarification as to whether Claim 28 should be considered to be included within Groups I or II.

Election:

In response to this Restriction, applicants hereby affirmatively elect the claims of Group I (i.e., Claims 1-28), with traverse, and subject to applicants' right to file one or more divisional applications directed to the non-elected inventions.

Effect of Amendments:

As noted by the Examiner, the claims are currently directed to apparatus claims, method claims directed to making an apparatus, and method claims directed at using an apparatus. Applicants have amended the claims herein to provide more correlation between the claims, in an attempt to enable the different types of claims to be examined together.

The apparatus claims encompass a model of a human head that includes a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture.

The process claims directed to making a medical model are now specifically directed to making models including a simulated patent suture that can be detected by ultrasound because of the



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echogenicity of the simulated patent suture.

The process claims directed at using a medical model for training are now specifically directed to using a model including a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture.

Because the claims are now directed to an apparatus, a method of making the apparatus, and a method of using the apparatus, there does not appear to be an undue burden on the Examiner in examining the claims together.

Traverse of the Restriction of Inventions I and III:

The Examiner asserts that the Inventions I and III are related as product and process. The Examiner specifically asserts, referring to MPEP 806.05(e), that the apparatus of Invention I can be used to perform other methods, such as teaching medical student to perform head positioning prior to an x-ray procedure, that is not the same as the method of Invention III.

MPEP 806.05(e) states: "*Process and apparatus for its practice can be shown to be distinct inventions, if either or both of the following can be shown: (A) that the process as claimed can be practiced by another materially different apparatus or by hand; or (B) that* ***the apparatus as claimed*** *can be used to practice another materially different process.*" (Emphasis added.)

Significantly, both the method and apparatus claims (Invention I and III) include the common element of a life sized model of a human head, the model including a plurality of simulated skull sutures disposed at anatomically correct locations (including a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture) . The Examiner is correct that a life sized model of a human head could be used to train medical student to perform correct head positioning prior to an x-ray procedure. However, the Examiner simply cannot ignore the additional structural elements recited in applicants' apparatus claims. MPEP 806.05(e) specifically requires determining if ***the apparatus as claimed*** *can be used to practice another materially different process* (emphasis added). The apparatus ***as claimed*** includes a plurality of simulated skull sutures disposed at anatomically correct locations, including a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture. Such structural elements provide absolutely no benefit with respect to the head positioning procedure identified by the Examiner, but are required to enable the apparatus to be used to implement the claimed method.



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The "apparatus as claimed" language of MPEP 806.05(e) appears to require the analysis as to whether an apparatus can be used for a different process to be performed such that the proposed additional use is logically related to the invention as claimed. Tools (i.e., apparatus) designed to implement a specific function can sometimes be used for other purposes. A cell phone *can* be used as a paperweight, but that is not a very logical use, because it ignores the functional elements of a cell phone that provide the cell phones communication utility. Clearly, the "apparatus as claimed" language of MPEP 806.05(e) requires that the additional use must be logical in light of *all of the structural and functional elements of the apparatus* (i.e., of the apparatus of claimed). In other words, use of the claimed apparatus for a materially different process must be analyzed in light of ***all*** of the elements in the claimed apparatus.

As noted above, the claimed apparatus includes functional structural elements (the simulated skull sutures including a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture) that are completely irrelevant to the additional process identified by the Examiner. As such, restriction based on such a use appears to be inconsistent with MPEP 806.05(e). Applicants respectfully request that either a materially different process be identified that logically relates to the apparatus as claimed (i.e., a use that requires the simulated skull sutures including a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture as present in the apparatus of Invention I), or that the claims encompassed by Groups I and III be examined together.

Traverse of the Restriction of Groups I and II:

The Examiner asserts that the Groups I and II are related as product made and process of making. The Examiner specifically asserts, referring to MPEP 806.05(f), that the apparatus of Group I can be made by a materially different process, such as molding a model of a human head including the simulated skull sutures.

Applicants respectfully submit that there is not a reasonable likelihood of success that the molded model can be used as an ultrasound simulator. The apparatus of Group I must not only include structural elements that visually resemble skull sutures, those simulated sutures must be discernable in an ultrasound image. For example, Claim 1 specifically states that *an echogenicity of each simulated patent skull suture enabling the simulated patent skull suture to be readily distinguishable in an ultrasound image of said model.*



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The method of Group II forms openings in a model of a head where patent sutures are to be simulated, because such openings can be identified in an ultrasound image. Claim 29 has been specifically amended to require that the model be made such that it includes a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture. For the patent suture, ultrasound responds differently to the material of the model and the lack of the material of the model (the openings). In the case of the molded model suggested by the Examiner, although the molded sutures could be visually observed, the molded sutures are not likely to be visible in an ultrasound image, because the echogenicity of the molded sutures will be reasonably equivalent to the echogenicity of the rest of the model (because the material of the model has not changed, just its shape/form). Ultrasound responds to significant changes in the density of a material (bone verses tissue, or the material of a skull model and voids/openings in the skull model). Because the molded model suggested by the Examiner would be substantially uniform as to its material composition, the molded sutures will be difficult to discern (the sutures will not have a different echogenicity) using ultrasound, even if the material used to generate the model is a bit thicker or thinner at the suture. Unless the material is changed to achieve a substantially different density (or more explicitly, a different echogenicity) at the simulated patent suture, the echogenicity will not be sufficiently different to enable the patent suture to be visible on an ultrasound scan.

Applicants respectfully request that either a materially different process for generating a model having a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture be identified, or that the claims encompassed by Groups I and II be examined together.

Traverse of the Restriction of Groups II and III:

The Examiner asserts that the Groups II and III are directed to related processes, referring to MPEP 806.05(j). The Examiner specifically asserts that the method of using a medical simulator of Invention III can be performed using a generic medical simulator (i.e., by a product made a process different than that encompassed by Invention II) with a reasonable expectation of success.

Applicants respectfully submit that MPEP 806.05(j) specifically states that "*To support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, both two-way distinctness* ***and reasons for insisting on restriction are***



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***necessary, i.e., separate classification, status in the art, or field of search***" (emphasis added). The Examiner has stated that Groups II and III are classified in Class 434, subclass 270. There is no evidence that Groups II and III have separate classification, status in the art, or field of search, thus restriction is improper per MPEP 806.05(j), and the claims of Groups II and III should be examined together.

Further, applicants respectfully submit that *there is not a reasonable likelihood of success* that the method of using a medical simulator of Group III can be performed using a generic medical simulator (i.e., by a product made a process different than that encompassed by Group II). The method of Group III requires a medical simulator molded model can be used as an ultrasound simulator, including the step of providing a model that includes a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture. The method of Group II is directed to making a model that includes a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture. There is simply no evidence that a generic medical simulator would include a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture, nor any evidence that a model including a simulated patent suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture could be made by any method other than the method of Group II. Thus, the claims encompassed by Groups II and III should be examined together.

In view of the amendment and the Remarks set forth above, it will be apparent that the claims in this application should be examined together, and that the restriction requirement should be withdrawn. Should any further questions remain, the Examiner is invited to telephone applicants' attorney at the number listed below.

Respectfully submitted,

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3000-3842-4536PT
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